K112496

510(k) SUMMARY

Pioneer IBF/VBR System

SEP 28 2011

Sponsor:	Manufacturer	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855
	Official Contact Phone: Fax:	Emily M. Downs (906) 225-5602 (906) 226-4459
	Date prepared:	September 28, 2011
Device Name:	Pioneer Interbody Fusion/Vertebral Body Replacement System	
Classification Name:	Intervertebral Body Fusion Device / Vertebral Spacer Device	
Classification Number:	21 CFR 888.3080 - product codes MAX and ODP, class II 21 CFR 888.3060 - product code MQP, class II	

Description: The **Pioneer IBF/VBR System** is an implantable device manufactured from PEEK and tantalum or titanium alloy that is available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

The purpose of the submission was to add the CrossFuse II device to the system.

Intended Use: The **Pioneer IBF/VBR System**, when used as an IBF implant, is indicated for intervertebral body fusion of the spine in skeletally mature patients. Pioneer IBFs are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. Pioneer IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level, such as the Quantum, Streamline, Contact ALP or SlimFuse systems.

The Cervical IBF device in intended for use at one level in the cervical spine, from C3 to T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment.

Lumbar IBFs are also intended for use at either one level or two contiguous

levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Lumbar IBFs are to be used in patients who have had six months of non-operative treatment.

The **Pioneer IBF/VBR System,** when used as a VBR implant, is intended for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. Pioneer VBRs are also indicated for treating fractures of the thoracic and lumbar spine. Pioneer VBRs are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The system must be used with the Pioneer® Quantum Spinal Fixation System or supplemental internal fixation systems cleared for the conditions listed above (i.e., tumor or trauma of T1-L5). Additionally, the Pioneer Vertebral Spacer implant is intended to be used with bone graft.

Material: The Pioneer IBF/VBR System are composed of Polyether ether ketone (PEEK) with tantalum or titanium alloy markers. The predicate device is composed of the same materials.

Comparison to Predicate Devices: The indication for use and material composition of the Pioneer IBF/VBR System are the same as the currently cleared predicate device, Pioneer IBF/VBR System (K043206/K061151/K073177). The differences in dimensional specifications between the subject devices and the predicate were not considered significant based on mechanical testing.

Performance Data: For a determination of substantial equivalence, the following non-clinical mechanical tests were performed:

- Static Compression
- Static Torsion
- Subsidence
- Expulsion

Performance and SE Determination: Based on the supporting documentation within this premarket notification, the subject device demonstrates substantial equivalence to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 28 2011

Pioneer Surgical Technology
% Ms. Emily M. Downs
375 River Park Circle
Marquette, Michigan 49855

Re: K112496
Trade/Device Name: Pioneer Interbody Fusion / Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP
Dated: August 24, 2011
Received: August 29, 2011

Dear Ms. Downs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112496

Device Name: **Pioneer Interbody Fusion /Vertebral Body Replacement System**

Indications:

The **Pioneer IBF/VBR System**, when used as an IBF implant, is indicated for intervertebral body fusion of the spine in skeletally mature patients. Pioneer IBFs are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. Pioneer IBFs are intended to be used with supplemental spinal fixation cleared for the implanted level, such as the Quantum, Streamline, Contact ALP or SlimFuse systems.

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Lumbar IBFs are also intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Lumbar IBFs are to be used in patients who have had six months of non-operative treatment.

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Prescription Use ___√___ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112496